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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,618	06/26/2006	Hiroyuki Kamiya	2006_1028A	9673

513 7590 02/03/2009

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
MINNIFIELD, NITA M	
ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
02/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,618	KAMIYA, HIROYUKI	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *12-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group I, claims 1-11, in the reply filed on November 5, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 12-19 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 5, 2008.

3. Receipt is acknowledged of papers (PCT/JP2004/017647 filed 11/19/04 and JP2003-431007 filed 12/25/03) submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. However, Applicant has not provided an English translation for either of these priority papers. Applicant cannot rely upon the foreign priority papers to overcome the rejections because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Sequence Requirements

4. This application contains sequence disclosures (see Table 1, page 17) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set

forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this office action. A complete response to this office action should include both compliance with the sequence rules and a response to the Non-Final Office Action set forth below. Failure to fully comply with ***both*** these requirements in the time period set forth in this office action will be held non-responsive.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1 and 3-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsuchiya et al (BBRC, 2005, 326:777-781).

Tsuchiya et al discloses unmethylated CpG dinucleotides in DAN contribute to a rapid inflammatory response in mammals (abstract). Tsuchiya et al discloses that "N^6-methyladenine (N^6-MeA), a bacterium-specific modified base, also causes cytokine production. An oligodeoxyribonucleotide (ODN) containing N^6-MeA induced cytokines when injected into mice. Co-injection of N^6-MeA and CpG ODNs enhanced cytokines 2- to 3-fold, as compared with the injection of a CpG ODN alone. Plasmid DNA containing N^6-MeA, complexed with cationic lipids, induced IL-12. These results indicate that the bacterium-specific base, in addition to the unmethylated CpG motif, triggers the mammalian immune response, and suggest that N^6-MeA-containing DNA could be useful for cellular immunotherapy and DNA vaccine." (Abstract; see also p. 777, right hand column; materials and methods, p. 778) Tsuchiya et al discloses both SEQ ID NO: 2 and 4 (Table 1, p. 778). The ODN-1 disclosed in Tsuchiya et al is claimed SEQ ID NO: 2 and ODN-4 disclosed in Tsuchiya et al is claimed SEQ ID NO: 4. The prior art anticipates the claimed invention of an immunopotentiator comprising a nucleic acid containing a special nucleic acid base, a derivative thereof or a plasmid having the nucleic acid containing the special nucleic acid base.

Since the Patent Office does not have the facilities for examining and comparing applicants' immunopotentiator with the immunopotentiator of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed immunopotentiator and the immunopotentiator of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. Claims 1, 3, 4, 6, 8, and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Ochiai et al (Biol. Pharm. Bull., 2005, 28/10:2019-2022).

Ochiai et al discloses that plasmid DNA containing N^6-methyladenine (N^6-MeA), a bacterium-specific modified base, induced cytokine twice as efficiently as plasmid DNA without N^6-MeA, when complexed with cationic lipids. Thus, plasmid DNA without N^6-MeA might express a transgene more efficiently than that containing N^6-MeA *in vivo* (abstract). The inflammatory response elicited by the DNA–cationic lipid complexes is thought to be due to unmethylated CpG sequences, because the unmethylated CpG dinucleotides in ODNs effectively induce cytokine production (p. 2019, left column) Ochiai et al discloses that an ODN containing N^6-methyladenine (N^6-MeA), a bacterium-specific modified base, induced cytokines (p. 2019, left column). The prior art anticipates the claimed invention of an immunopotentiator comprising a nucleic acid containing a special nucleic acid base, a derivative thereof or a plasmid having the nucleic acid containing the special nucleic acid base.

Since the Patent Office does not have the facilities for examining and comparing applicants' immunopotentiator with the immunopotentiator of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed immunopotentiator and the immunopotentiator of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

9. Claims 1, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Brunner et al (J. Immunology, 2000, 165:6278-6286).

Brunner et al discloses CpG containing oligonucleotides, which mimic the immunostimulatory effect of bacterial DNA (abstract). Brunner et al discloses that these oligonucleotides induce cytokine production (abstract). Brunner et al discloses that synthetic oligodeoxynucleotides containing unmethylated cytidine-phosphate-guanosine (CpG) dinucleotides (CpG-ODN) in specific sequence contexts mimic the immunostimulatory qualities of bacterial DNA. In vitro, they up-regulate the expression of costimulatory and Ag-presenting molecules and the secretion of IL-12 by monocytcs and DC. In vivo, CpG-ODN act as an adjuvant, promoting Thl immune responses that can enhance promotion from a subsequent tumor challenge when coadministered with tumor Ag." (p. 6278, right column) Brunner et al discloses in vitro methods of producing an inflammatory cytokine (i.e. TNF-α, IL-12) using cultured cells (materials and methods). The prior art anticipates the claimed invention.

10. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Karras (7307369, filing date 02/06/04).

Karras discloses a nucleic acid containing a special nucleic acid base or derivative thereof (see description, para. 34 and 113). Karras discloses that the modified nucleobase (i.e. special nucleic acid base). "Oligomeric compounds may also include nucleobase (often referred to in the art simply as "base" or ("hetero-cyclic base moiety") modifications or substitutions. As used herein, "unmodified" or "natural" nucleobases include the purine bases adenine (A) and guanine (G), and the pyrimidine bases thymine (T), cytosine (C) and uracil (U). Modified nucleo-bases also referred herein as heterocyclic base moieties include other synthetic and natural nucleobases such as 5-methylcytosine (5-me-C), 5-hydroxymethyl

cytosine, xanthine, hypoxanthine, 2-aminoadenine, 6-methyl and other alkyl derivatives of adenine and guanine, 2-propyl and other alkyl derivatives of adenine and guanine, 2-thiouracil, 2-thiothymine and 2-thiocytosine, 5-halouracil and cytosine, 5-propynyl (-C=C-CH_3) uracil and cytosine and other alkynyl derivatives of pyrimidine bases, 6-azo uracil, cytosine and thymine, 5-uracil (pseudouracil), 4-thiouracil, 8-halo, 8-amino, 8-thiol, 8-thioalkyl, 8-hydroxyl and other 8-substituted adenines and guanines, 5-halo particularly 5-bromo, 5-trifluoromethyl and other 5-substituted uracils and cytosines, 7-methylguanine and 7-methyladenine, 2-F-adenine, 2-amino-adenine, 8-azaguanine and 8-azaadenine, 7-deazaguanine and 7-deazaadenine and 3-deazaguanine and 3-deazaadenine." (description, para. 113)

It is noted that the specification broadly describes a derivative thereof: "In the invention of this application, the derivative of the nucleic acid containing the special nucleic acid base may be used. This "derivative" is a substance whose phosphoric acid moiety or sugar moiety is modified in using a chemical synthetic product, a substance with a structure other than a base moiety changed or the like." (p. 12, l. 1-7) The prior art anticipates the claimed invention.

Since the Patent Office does not have the facilities for examining and comparing applicants' products with the products of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed products and the products of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

11. No claims are allowed.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. M. Minnifield/
Primary Examiner, Art Unit 1645
January 30, 2009